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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,292	03/21/2001	Borge Kringelum	030307- 0197	1783

22428 7590 04/08/2003

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EXAMINER
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DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/813,292

Applicant(s)

KRINGELUM ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's amendment and request for continued examination filed January 17, 2003, has been received and entered into the case. All arguments have been fully considered.

#### *Claim Objections*

Claim 1 is objected to because of the following informalities: In line 5, "hereof" should be spelled correctly as "thereof". Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 – 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a method for supplying a starter culture, however are rendered vague and indefinite for reciting "when required" because it is unclear if the limitations following the phrase are required limitations, or if they are merely optional to the method.

The claims are further indefinite because the method is for supplying a starter culture, however, step (iii) merely recites the starter culture is supplied by "supplying" inoculum

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material. It appears that applicant has failed to delineate the invention from other methods for supplying a starter culture.

In claim 1 line 8, the recitation of "using" is indefinite because it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Applicant may prefer to replace the term "using" with the positive step occurring in the method (i.e. inoculating a subset...).

The claims are further confusing for reciting "at said customer" because it is unclear what applicant intends to convey by the limitation.

Claim 19 is rendered vague and indefinite for reciting "step (I)". Applicant may prefer to replace "(I)" with "(i)" to more clearly claim the invention.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 7, 11, 17 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

- i) providing a stock inoculum material comprising a concentrate of starter culture cells,
- ii) dividing the inoculum material into subsets,
- iii) supplying inoculum material subsets to customers,
- iv) inoculating the subset into a cultivation medium for propagating the subset cells to a desired amount of cells, and
- v) harvesting the propagated cells to obtain a starter culture,

wherein the method provides cells of consistent quality when steps iv – v are performed with the divided inoculum material subsets. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least  $10^8$  CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium,

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Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first divided into subsets and distributed to customers. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to divide the inoculum into subsets as a matter of routine practice. Although the reference does not teach distributing the subsets to customers, the step does not appear critical to the invention as the method is drawn to a method of culturing

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cells, not a business method for distribution of cultures. Moreover, such a distribution step would appear to be commonplace in the art, for example when acting as a depository.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

6. Claims 1– 7, 11, 17 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

- i) providing a stock inoculum material comprising a concentrate of starter culture cells,
- ii) dividing the inoculum material into subsets,
- iii) supplying inoculum material subsets to customers,
- iv) inoculating the subset into a cultivation medium for propagating the subset cells to a desired amount of cells, and
- v) harvesting the propagated cells to obtain a starter culture,

wherein the method provides cells of consistent quality when steps iv – v are performed with the divided inoculum material subsets. The stock inoculum of step i) is a quantity sufficient



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to inoculate at least 50,000 liters of culture medium or at least  $10^8$  CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are



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named to include *Lactococcus* (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first divided into subsets and distributed to customers. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to divide the inoculum into subsets as a matter of routine practice. Although the reference does not teach distributing the subsets to customers, the step does not appear critical to the invention as the method is drawn to a method of culturing cells, not a business method for distribution of cultures. Moreover, such a distribution step would appear to be commonplace in the art, for example when acting as a depository.

Sing does not teach the culture medium comprising skimmed milk. However, Czulak teaches a method of inoculating milk with a fat content of 0.3 – 1.5% (part skim and low fat milk) to produce cheese (abstract). Czulak teaches that use of skim milk enables a cheese product to be made with a substantially reduced fat content (col.1 line 10-15). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Czulak to use a culture medium including at least part skim milk in the method of Sing with a reasonable expectation of success for obtaining a dairy product with a reduced fat content.

The above references do not teach each of the claimed “quantities sufficient”, rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the

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amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

7. Claims 1 – 11, 17 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

- i) providing a stock inoculum material comprising a concentrate of starter culture cells,
- ii) dividing the inoculum material into subsets,
- iii) supplying inoculum material subsets to customers,
- iv) inoculating the subset into a cultivation medium for propagating the subset cells to a desired amount of cells, and
- v) harvesting the propagated cells to obtain a starter culture,

wherein the method provides cells of consistent quality when steps iv – v are performed with the divided inoculum material subsets. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least  $10^8$  CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium,

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Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum material or subset is liquid, frozen, or dried; the frozen inoculums are first thawed before inoculation; and the subsets is combined with an aqueous medium to obtain a suspension before cultivating. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first divided into subsets and distributed to customers. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to divide the inoculum into subsets as a matter of routine practice. Although the reference does not teach distributing the subsets to customers, the

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step does not appear critical to the invention as the method is drawn to a method of culturing cells, not a business method for distribution of cultures. Moreover, such a distribution step would appear to be commonplace in the art, for example when acting as a depository.

Sing does not teach the methods wherein the inoculums are liquid, frozen or dried; wherein a frozen inoculum is thawed and a dried subset is combined with an aqueous medium before inoculating into the culture medium. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to do so as a matter of routine practice. In support, Lizak teaches conventional storage of starting cultures includes liquid culture, frozen culture and dried culture (col.6 line 53-59). Although Lizak does not specifically teach frozen cultures are thawed and dried cultures are suspended in a liquid medium before inoculation, it was well known in the art to do so at the time of the invention. Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain stock inoculum and/or subset cultures as a liquid, frozen or dried, thaw it and/or suspend the dried culture in a liquid medium because it was routine in the art as demonstrated by Lizak.

The references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

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8. Claims 1 – 7, 11 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Vandenberg and Matsumiya.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

- i) providing a stock inoculum material comprising a concentrate of starter culture cells,
- ii) dividing the inoculum material into subsets,
- iii) supplying inoculum material subsets to customers,
- iv) inoculating the subset into a cultivation medium for propagating the subset cells to a desired amount of cells, and
- v) harvesting the propagated cells to obtain a starter culture,

wherein the method provides cells of consistent quality when steps iv – v are performed with the divided inoculum material subsets. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least  $10^8$  CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus,

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Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum is supplied in a sealed enclosure, made from a flexible material selected from polyolefin, substituted olefin, copolymer of ethylene, polypropylene, polyethylene, polyester, polycarbonate, polyamide, acrylonitrile and a cellulose derivative; a metal foil; has a content of at least 0.01 liters; has an outlet for connecting to the culture medium container, which allows for aseptic inoculation. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first divided into subsets and distributed to customers. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to divide the inoculum into subsets as a matter of routine practice. Although the reference does not teach distributing the subsets to customers, the



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step does not appear critical to the invention as the method is drawn to a method of culturing cells, not a business method for distribution of cultures. Moreover, such a distribution step would appear to be commonplace in the art, for example when acting as a depository.

Sing does not teach that the stock inoculum is provided in a sealed enclosure as claimed. However, Vandenberg teaches starter cultures can be stored in leak-proof containers such as a plastic bag, plastic container, metal foil, or sealable containers (col.4 line 30-40). While Vandengergh does not teach the material used or size of such containers, Matsumiya discloses cell culture containers made from ethylene copolymers, polyethylene, polypropylene, acrylonitrile copolymers (col.1 line 30-37). In addition, Matsumiya teaches that the flexible, bag like structures have an inlet tube and an outlet tube with a coupler at its end (col.1 line 23-30). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to provide a stock inoculum in a sealed enclosure because it was well known in the art to do so as demonstrated by Vandengergh and Matsumiya. Furthermore, it would have been well within the purview of one of ordinary skill in the art to optimize the capacity of such containers to correspond with volume of the culture as a matter of routine practice.

The references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.



9. Claims 1 – 7, 11, 17 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

- i) providing a stock inoculum material comprising a concentrate of starter culture cells,
- ii) dividing the inoculum material into subsets,
- iii) supplying inoculum material subsets to customers,
- iv) inoculating the subset into a cultivation medium for propagating the subset cells to a desired amount of cells, and
- v) harvesting the propagated cells to obtain a starter culture,

wherein the method provides cells of consistent quality when steps iv – v are performed with the divided inoculum material subsets. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least  $10^8$  CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus,

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Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first divided into subsets and distributed to customers. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to divide the inoculum into subsets as a matter of routine practice. Although the reference does not teach distributing the subsets to customers, the step does not appear critical to the invention as the method is drawn to a method of culturing cells, not a business method for distribution of cultures. Moreover, such a distribution step would appear to be commonplace in the art, for example when acting as a depository.

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Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein each of the named organisms are used. However, at the time of the claimed invention, each of the claimed organisms were well known and used in the art as sources of starter cultures. In support, Czulak teaches a method of inoculating milk with *Lactobacillus* and *Streptococcus* cultures whereby the cultures produce a desired cheese flavor (abstract). In further support, Lizak teaches starter cultures of fungus, *Bacillus*, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by routine practice to use the above named microorganisms in the method of Sing with a reasonable expectation of successfully obtaining a starter culture.

10. Claims 1 – 7, 11, 17 – 23 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Rimler and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

- i) providing a stock inoculum material comprising a concentrate of starter culture cells,

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- ii) dividing the inoculum material into subsets,
- iii) supplying inoculum material subsets to customers,
- iv) inoculating the subset into a cultivation medium for propagating the subset cells to a desired amount of cells, and
- v) harvesting the propagated cells to obtain a starter culture,

wherein the method provides cells of consistent quality when steps iv – v are performed with the divided inoculum material subsets. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least  $10^8$  CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least  $10^5$  CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriaceae, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

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Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least  $10^9$  CFU/g to a culture medium, growing the cells resulting in a medium with at least  $10^7$  CFU/g, propagating the cells to produce a starter culture with  $10^9$  CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include *Lactococcus* (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first divided into subsets and distributed to customers. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to divide the inoculum into subsets as a matter of routine practice. Although the reference does not teach distributing the subsets to customers, the step does not appear critical to the invention as the method is drawn to a method of culturing cells, not a business method for distribution of cultures. Moreover, such a distribution step would appear to be commonplace in the art, for example when acting as a depository.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

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Sing does not teach the method wherein the starter cells are used in the pharmaceutical industry and express a desired gene product such as an enzyme, pharmaceutically active substance, polysaccharide or amino acid. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because it was a well known practice in the art at the time the invention was made. In support, Rimler teaches a method of propagating starter cells of *Haemophilus* in order to obtain products useful as immunological agents (abstract). Stock cultures of the bacteria are passed twice (or propagated, sub-cultured and propagated), cultured in a medium, inoculated into a starter culture tube and propagated (col.3 line 1-15) to obtain the desired pharmaceutically active substance. In further support, Lizak teaches starter cultures of fungus, *Bacillus*, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain a desired gene product via the methods of Sing.

Applicant argues that the references do not teach dividing the inoculum into subsets and distributing them to customers, and that they do not teach maintaining a consistent quality of cells by dividing the cells into subsets. Specifically that Sing does not teach supplying cultures with consistent quality, and high stability. Applicant provides a reference supporting that liquid cultures lose their activity with time, and that the references do not teach or suggest a retained stability and activity for up to 5 years in liquid cultures.

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However these arguments fail to persuade because as stated above, such dividing and distribution steps do not appear critical to the invention, as the claims are drawn to a method for supplying starter cultures, not a business method for distributing cultures. Furthermore, such steps of dividing and distributing are commonplace in depositories, for example, where seed (or starter) cultures are first divided, distributed to customers and later propagated.

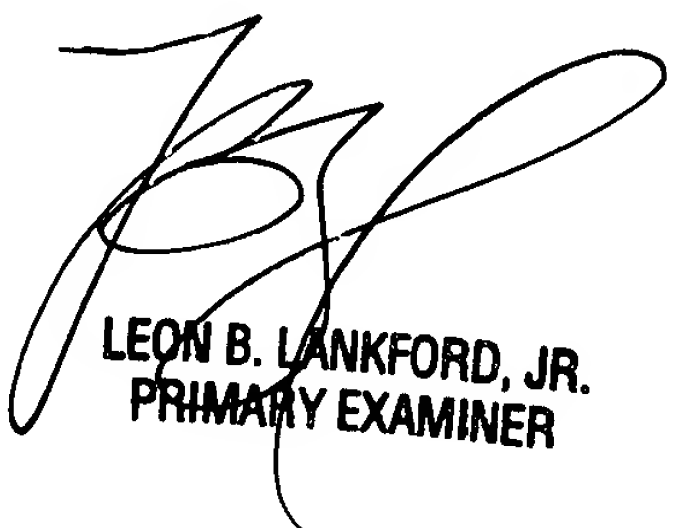
Regarding applicant's argument drawn to liquid cultures, it is noted that the claims do not require liquid cultures of lactic acid bacteria. The claims are drawn to ANY starter culture with ANY activity and/or effect.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
April 2, 2003



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER